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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/034,782	12/27/2001	Lisa M. Parker	580755.003	9050
27910	7590	04/19/2005		
STINSON MORRISON HECKER LLP ATTN: PATENT GROUP 1201 WALNUT STREET, SUITE 2800 KANSAS CITY, MO 64106-2150			EXAMINER MITCHELL, TEENA KAY	
			ART UNIT	PAPER NUMBER
			3743	

DATE MAILED: 04/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

SP

Office Action Summary	Application No. 10/034,782	Applicant(s) PARKER ET AL.	
	Examiner Teena Mitchell	Art Unit 3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-23 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 February 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Neidhart et.al. (3,658,058).

Neidhart in a mouthpiece discloses:

- a flexible disk (4) configured to fit between a user's teeth and lips (Fig. 1); and
- a bite block extending from an interior surface of said disk (at 5), wherein said bite block comprises:
 - an arm extending substantially perpendicular to the interior surface of said disk (See illustration of Fig. 3 below); and
 - a flange extending substantially perpendicular to said arm (See illustration of Fig. 3 below).

The difference between Neidhart and claim 12 is the width of said arm and the width of said flange being less than or substantially equal to 15 mm.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have the width of said arm and the width of said flange being less than or substantially equal to 15 mm. because regardless of what the width of the arm and flange the device is held in the users mouth on the width of the arm and flange and one of ordinary skill would know that different size width's for the arm and flange would be required for different sized individuals.

Furthermore, applicant has not disclosed that having the width of said arm and the width of said flange being less than or substantially equal to 15 mm provides an advantage, is used for a particular purpose, or solves a stated problem. Therefore, it would have been obvious an obvious matter of design choice to modify Moulton to obtain the invention as specified in claim 12.

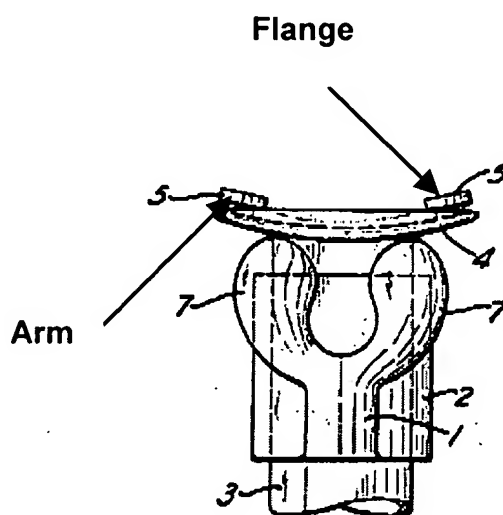


Fig. 3

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Neidhart ('058) in view of Anderson (5,893,365).

The difference between Neidhart and claim 13 is the thickness of the disk being less than or substantially equal to 1.5 mm.

Anderson in a mouthpiece device teaches a silicone rubber material used in a mouthpiece disk (24) wherein the thickness of the disk is less than or substantially equal to 1.5 mm (Col. 6, lines 4-10).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have the thickness of the disk being less than or substantially equal to 1.5 mm (Col. 6, lines 4-10) because the disk of Neidhart is made of a rubber material and Anderson teaches that a rubber disk can be have a thickness of being less than or substantially equal to 1.5 mm. Furthermore, applicant has not disclosed that having the thickness of the disk being less than or substantially equal to 1.5 mm provides an advantage, is used for a particular purpose, or solves a stated problem. Therefore, it would have been obvious an obvious matter of design choice to modify Moulton to obtain the invention as specified in claim 13 and inasmuch as such a thickness is taught by Anderson.

Claims 14, 23, 2-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neidhart/Anderson as applied to claims 1 and 13 above, and further in view of Vigilia (4,881,540).

The difference between Neidhart and claim 14 is the material of the disk being a material that naturally adheres to the interior of the user's lips and cheeks.

Vigilia in a mouthpiece teaches a mouthpiece made of a material that naturally adheres to the lips and cheeks of a user (30) with a viscous or otherwise sealing material providing an enhancing seal (Col. 3, lines 44-47).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Neidhart to employ any well known disk material that naturally adheres to the interior of the user's lips and cheeks doing so would have provided a material which enhances the seal including the material taught by Vigilia.

With respect to claims 2 and 3, note rejection of claim 13 above.

With respect to claim 4, note rejection of claim 14 above.

With respect to claims 6-9, note rejection of claim 12 above.

With respect to claim 5, Neidhart discloses the claimed invention except for the disk comprised of silicone. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the disk of silicone, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of choice, absent persuasive evidence that using a silicone has an advantage, is used for a particular purpose, or solves any particular problem. In re Leshin, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

With respect to claim 23, note rejections of claims 12, 13, and 14 above

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Claims 15, 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neidhart et.al. ('058) as applied to claim 12 above, and further in view of Moulton (746,869).

The difference between Neidhart and claim 15 is a one-way valve in said disk configured to allow air to pass through said disk from an exterior to an interior of said disk.

Moulton in a mouthpiece teaches a one-way valve (2) providing a means for preventing the ingress of air through the mouth when breathing and to regulate its egress, so as to cause the air to be admitted to the lungs and expelled therefrom in the natural manner through nasal passages (Col. 1, lines 30-45).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the mouthpiece of Neidhart to employ any well known valve doing so would have provided a means for preventing the ingress of air through the mouth when breathing and to regulate its egress, so as to cause the air to be admitted to the lungs and expelled therefrom in the natural manner through nasal passages including the one-way valve taught by Moulton.

With respect to claims 10 and 11, note rejection of claim 15 above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which

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said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Moulton (746,869) in view of Vigilia (4,881,540).

Moulton in a mouthpiece discloses a flexible disk configured to fit between a user's teeth and lips (Fig. 1); and a one-way valve (2) in said disk configured to allow air to pass through said disk from an exterior of said disk to an interior of said disk.

The difference between Moulton and claim 16 is the material of the disk being a material that naturally adheres to the interior of the user's lips and cheeks.

Vigilia in a mouthpiece teaches a mouthpiece made of a material that naturally adheres to the lips and cheeks of a user (30) with a viscous or otherwise sealing material providing an enhancing seal (Col. 3, lines 44-47).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Moulton to employ any well known disk material that naturally adheres to the interior of the user's lips and cheeks doing so would have provided a material which enhances the seal including the material taught by Vigilia.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 17, 19, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pantino (5,832,918) in view of Vent and Saliva Shield (Handout).

Pantino in a mask (10) cover the user's nose, wherein said mask is affixed to an air source (at 130).

The difference between Pantino and claim 17 is inserting a mouthpiece into the user's mouth.

Vent Saliva Shield teaches providing a mouthpiece (Fig) providing a means to prevent mouth breathing and drying of mucous membranes in the mouth and preventing venting when CPAP is worn.

It would have been obvious one of ordinary skill in the art at the time the invention was made to modify the mask of Pantino to employ any well known mouthpiece and insert at least a portion of a mouthpiece into a user's mouth doing so would have provided a means to prevent mouth-breathing and drying of mucous membranes in the mouth and preventing venting when CPAP is worn as taught by the Vent and Saliva Shield handout.

With respect to claim 19, Vent and Saliva Shield teaches a bite block (note white area in Fig) affixed to an interior surface of said mouthpiece, configured to position the user's lower jaw in a position that maintains an open airway.

With respect to claim 20, Vent and Saliva Shield teaches an arm (at front of mouthpiece) extending substantially perpendicular to the interior surface of said

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mouthpiece and a flange (note white area in Fig) extending substantially perpendicular to said arm.

The difference between Vent and Saliva Shield and claim 20 is the width of said arm and the width of said flange being less than or substantially equal to 15 mm.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have the width of said arm and the width of said flange being less than or substantially equal to 15 mm. because regardless of what the width of the arm and flange the device is held in the users and one of ordinary skill would know that different size width's for the arm and flange would be required for different sized individuals.

Furthermore, applicant has not disclosed that having the width of said arm and the width of said flange being less than or substantially equal to 15 mm provides an advantage, is used for a particular purpose, or solves a stated problem. Therefore, it would have been obvious an obvious matter of design choice to modify the mouthpiece to obtain the invention as specified in claim 20.

Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pantino/Vent and Saliva Shield as applied to claim 17 above, and further in view of Moulton (746,869).

The difference between Vent/Saliva Shield and claim 21 is a one-way valve in said disk configured to allow air to pass through said disk from an exterior to an interior of said disk.

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Moulton in a mouthpiece teaches a one-way valve (2) providing a means for preventing the ingress of air through the mouth when breathing and to regulate its egress, so as to cause the air to be admitted to the lungs and expelled therefrom in the natural manner through nasal passages (Col. 1, lines 30-45).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the mouthpiece of to employ any well known valve doing so would have provided a means for preventing the ingress of air through the mouth when breathing and to regulate its egress, so as to cause the air to be admitted to the lungs and expelled therefrom in the natural manner through nasal passages including the one-way valve taught by Moulton.

With respect to claim 22, note rejection of claim 21 above.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pantino/Vent and Saliva Shield as applied to claim 17 above, and further in view of Vigilia (4,881,540).

The difference between Vent and Saliva Shield and claim 18 is the material of the disk being a material that naturally adheres to the interior of the user's lips and cheeks.

Vigilia in a mouthpiece teaches a mouthpiece made of a material that naturally adheres to the lips and cheeks of a user (30) with a viscous or otherwise sealing material providing an enhancing seal (Col. 3, lines 44-47).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the mouthpiece of Vent and Saliva Shield to employ any

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well known disk material that naturally adheres to the interior of the user's lips and cheeks doing so would have provided a material which enhances the seal including the material taught by Vigilia.

Response to Arguments

Applicant's arguments filed 1/24/05 have been fully considered but they are not persuasive. Applicant argues that Neidhart does not disclose a disk. However, based on standard dictionary definition of a disk (i.e., a thin, flat, circular plate) and the figures of the instant application, Neidhart discloses a disk (at reference element 4). Applicant is also arguing function limitations, which are not present in the claims. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Vigilia is provided for the teaching of a material, which naturally adheres, a viscous or otherwise sealing material providing an enhancing seal (Col. 3, lines 44-47). Inasmuch as claim 16 merely states, "A mouthpiece for preventing air leakage" the use of the material taught by Vigilia in the mouthpiece of Moulton would provide a material that naturally adheres, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of design consideration

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and one would look to the material taught by Vigilia to provide a material which naturally adheres to the interior of the user's lips and cheeks.

Applicant states that the Vent and Saliva Shield do not meet the time limitations for a 102 (b), however the reference does fall within less than one year which constitutes a 102(e) date, and is usable in a 103 rejection, the examiner did not use the reference for a 102 (b) rejection. Therefore, applicant's argument is not persuasive.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teena Mitchell whose telephone number is (571) 272-4798. The examiner can normally be reached on Monday-Friday however the examiner is on a flexible schedule.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Teena Mitchell
Examiner
Art Unit 3743
April 14, 2005